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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/604,985	08/29/2003	Itzhak Bentwich	06087.0200.CPUS12	1984
37808	7590	05/25/2006	EXAMINER	
ROSETTA-GENOMICS 10 PLAUT-STREET SCIENCE PARK P.O. BOX 2061 REHOVOT, 76706 ISRAEL			WOLLENBERGER, LOUIS V	
			ART UNIT	PAPER NUMBER
			1635	
DATE MAILED: 05/25/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/604,985

Applicant(s)

BENTWICH, ITZHAK

Examiner

Louis V. Wollenberger

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 25 January 2006 and 10 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 4, 5 and 7-21 is/are pending in the application.
- 4a) Of the above claim(s) 11, 12 and 15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1, 2, 4, 5, 7-10, 13, 14, and 16-21 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)                                    | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Location of the Application***

The location of the application has changed. The application is now located in Art Unit 1635 and has been docketed to Examiner Louis V. Wollenberger.

### ***Election/Restrictions***

Applicant's election with traverse of SEQ ID NO:1 in the reply filed on January 25, 2006, is acknowledged. However, in view of Applicant's amendments to the claims the following further Restriction is required and is set forth below.

### ***Status of the application***

With the amendment submitted on 1/25/06, and resubmitted in compliant form on 4/10/06, Claims 1, 2, 4, 5, and 7–21 are pending. Claims 11, 12, and 15 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claims 1, 2, 4, 5, 7–10, 13, 14, and 16–21 are subject to restriction as follows.

### ***Election/Restrictions***

Applicant's amendments to the claims necessitate the following Restriction Requirement.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

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- I. Claims 1, 4, 10, 13, 14, 16, and 19-21, drawn to an isolated nucleic acid comprising SEQ ID NO:1, including the complement thereof, and to a gene encoding SEQ ID NO:1, and to a vector comprising SEQ ID NO:1, and to gene expression inhibition and detection systems comprising SEQ ID NO:1 classified in class 536, subclass 23.1.
- II. Claims 2, 5, 7-9, and 17-21, drawn to an isolated RNA, 18 to 24, 50 to 77, or about 22 nucleotides in length, including the complements thereof, wherein the RNA is capable of modulating the expression of a target gene, classified in class 536, subclass 24.5.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are directed to related products. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the claimed DNA and RNA products are distinct in that they do not overlap in scope; they are not capable of use together, and they have materially different designs, modes of operation, function and effect. For example, Group II comprises claims to isolated RNAs of 18 to 24 nucleotides in length and embrace antisense RNAs and double-stranded interfering RNAs, which have a materially different designs, structures, and modes of action, function, and effect in the cell as compared to the isolated nucleic acids and vectors of Group I. While the DNA of Group I may be manipulated so as to produce antisense

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molecules, the long antisense molecules of Group I will have a different mode of action, potency, and biological behavior in the cell as compared to the short, interfering RNAs of Group II, which operate through the RISC pathway and are normally comprised of double stranded RNAs.

Furthermore, the nucleic acids of claim 1 of Group I encompass much more than just SEQ ID NO:1, in that the claim recites open, "comprising" language, which reads on a multitude of possible nucleic acids, DNA sequences, and expression constructs of almost any length having a wide variety of nucleotide sequences and a broad array of biological functions unrelated to that of the isolated RNA of Group II. A DNA sequence comprising SEQ ID NO:1 may be used for materially different and non-overlapping purposes outside the scope of Group II. For example, the DNA of Group I may be used for the production of recombinant proteins or peptides for use in antigenic, immuno stimulating, antibody production, or gene therapy purposes that have an entirely different function and effect as compared to the gene suppression effects of the antisense and short interfering RNAs of Group II.

Thus, because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, divergent subject matter, and require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

### ***Conclusion***

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

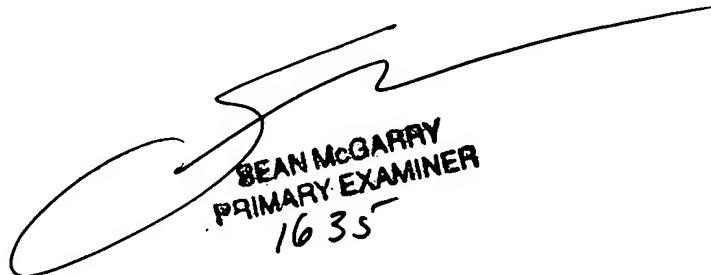
Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louis V. Wollenberger whose telephone number is 571-272-8144. The examiner can normally be reached on M-F, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571)272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Louis Wollenberger  
Examiner, Art Unit 1635  
May 23, 2006



SEAN MCGARRY  
PRIMARY EXAMINER  
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